

Quality Manual

Revision:

Approval:

Table of contents

1. Scope
2. Normative references
3. Terms and Definitions
4. Quality Management System
5. Management responsibility
6. Resource Management
7. Product Realization
8. Measurement Analysis and Improvement
9. References

1. Scope

- Exclusions from regulation (IE. ISO 13485)

2. Normative references

3. Terms and Definitions

4. Quality Management System

- General requirements
- Documentation requirements

5. Management responsibility

- Management commitment
- Customer focus
- Quality policy
- Planning
- Responsibility, authority, and communication
- Management Review

6. Resource Management

- Provision of resources
- Human Resources
- Infrastructure
- Work environment

7. Product Realization

- Planning of product realization
- Customer related processes
- Design and development
- Purchasing
- Product and service provision
- Product and service provision

8. Measurement Analysis and Improvement

- General
- Monitoring and measurement
- Control of nonconforming product
- Analysis of data
- Improvement

9. References to

- relevant documents
- relevant appendices
- relevant attachments